REMARKS/ARGUMENTS

Applicant notes with appreciation that the finality of the last Office Action has been withdrawn. Applicant further notes with appreciation that the arguments submitted July 21, 2008 have been fully considered and have deemed persuasive and further that the rejection of claims 1, 3-10 and 12-14 under Robitaille et al. in view of Hennebert et al. have been withdrawn.

Claims 3 and 12 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite as failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. According to the Examiner, claims 3 and 12 further limit the "inert gas" of claims 1 and 6, respectively, to "oxygen." The Examiner considers such a limitation vague and indefinite since oxygen is not an inert gas, as it is a reactive gas. Applicant respectfully points out that this term "inert gas" has not been used to indicate a number of gases of the periodic table called the inert gases. Rather, it has been used to indicate a gas which is inert in the context of the sterilization process. That is, "inert gas" is used in the sense of being a gas which will not interfere with the sterilization process and, more specifically, it is a gas which will not form undesirable oxygenated products by contact with ozone. In order to expedite prosecution of this application, the term "inert gas" has been deleted and replaced with the wording: "a gas that does not form oxygenated products by contact with ozone." Support for this amendment can be found on pages 6 and 11 of the subject application. In view of these amendments to the claims, Applicant respectfully requests that the rejection under 35 U.S.C. § 112, second paragraph be withdrawn.

Claims 1, 3-10 and 12-14 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Robitaille et al. (U.S. Patent Application Publication No. 2002/0085950) in view of Childers et al. (U.S. Patent No. 5,527,508). According to the Examiner, Robitaille et al. discloses all the limitations of claims 1 and 6 except that Robitaille et al. is silent with respect to removing condensation during the sterilization cycle between consecutive exposures to humidified ozone. To address this deficiency,

the Examiner relies on Childers et al. stating that Childers et al. discloses a method of gaseous sterilization including repeated cycles of a vacuum, injection of a sterilant, and injection of an inert gas. The Examiner cites column 6, lines 14-30. The Examiner also notes that the injection of an inert gas into the chamber drives the sterilant vapor into closed or open ended lumens, while the step of drawing a vacuum removes residual sterilant vapors and humidity, thus preparing the system for the next sterilization pulse. The Examiner cites column 6, lines 57-62 in support of this position. The Examiner considers it to have been obvious to one of ordinary skill in the art to inject or "flush" the sterilization chamber of Robitaille et al. with inert gas in view of Childers et al. in order to drive the sterilant vapor into the lumens of instruments sterilized by Robitaille et al. This rejection is respectfully traversed.

The Robitaille et al. reference deals with ozone sterilization methods. When considered against conventional sterilization methods, ozone sterilization is considered to show the most promise as a quick, effective and safe sterilization procedure. However, according to the Robitaille et al. disclosure, using ozone alone is not reliable. Therefore, in order to achieve reliable sterilization, it is known that there must be water present and, in particular, a high humidity level. See paragraph 0006 of Robitaille et al. As discussed in Robitaille et al., even the extremely high humidity level of 85% is not consistently reliable and a preferred humidity for reliability is above 90%, and preferably 100%. See paragraph 0016 of Robitaille et al. The Robitaille et al. reference represented a substantial breakthrough in realizing the potential of ozone sterilization coupled with the application of a reduced pressure step to provide an effective means to achieve the high humidity levels needed.

Certainly, Robitaille et al. is a good starting place for the present invention. As such, Robitaille et al. sets forth, as can best be seen in Figure 3, a method for ozone sterilization. By comparing Figure 1 of the subject application to Figure 3 of Robitaille et al., one can clearly see that vacuum step 101 is analogous to vacuum step 4; humidification step 102 is analogous to humidifying step 5; ozone injection step 103 is analogous to ozone fill step 6; humidified ozone exposure/sterilization step 104 is

analogous to ozone exposure step 7; and step 106, which repeats the sterilization cycle, is analogous to step 8 of Robitaille et al. However, the inclusion of a reconditioning step 105 provided after step 104 in accordance with the present invention, wherein the chamber is flushed with an inert gas, is not in Robitaille et al.

The Childers et al. reference, on the other hand, is not concerned with ozone sterilization. Although it mostly refers to a "sterilant" without specifying any particular sterilant, it is clear that the intended sterilant is hydrogen peroxide. As such, the teachings of Robitaille et al. and Childers et al. are not compatible. Simply put, one would not look to the hydrogen peroxide sterilization of Childers et al. to modify the ozone sterilization system of Robitaille et al. In particular, ozone sterilization is completely different from any of the other conventional types of sterilization, including hydrogen peroxide sterilization. In ozone sterilization, the sterilant has two components: ozone and water vapor. The water vapor, in terms of its relative humidity, must be controlled with extreme precision in order to ensure the high humidity levels needed to achieve effective sterilization when using ozone. A need for such precision and controlling humidity does not exist in a hydrogen peroxide sterilization process nor in any of the other conventional sterilization processes. In most conventional sterilization procedures in which water is used, it is used in the form of steam and is used only for the purpose of controlling the temperature. That is, in order to heat articles to be sterilized. Therefore, precision control of humidity is not needed.

One of the many problems with the known ozone sterilization process is that, although a high relative humidity is needed for successful sterilization, the presence of any condensation on the articles to be sterilized will act as a barrier to the sterilization of the surface carrying the condensation. Therefore, prior to an application of a sterilization process, great efforts are made before the beginning of the sterilization in order to equilibrate the temperature in the sterilization chamber and its contents to avoid any condensation. Therefore, when it was discovered that sterilization was failing more than anticipated, the cause of the failure was not one of mystery, but was not attributed to

condensation. Therefore, the discovery that an additional flushing step to remove condensation between sterilization cycles represents a real break through in the art.

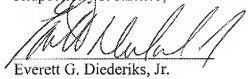
In addition, the purpose of the purported flushing step as characterized by the Examiner in the Childers et al. reference is quite different from that of the present application. The problem which is addressed by the Childers et al. reference is the problem of a failure of penetration by the sterilant. According to the reference, if the problem of penetration can be solved, then sterilization can be more effective in articles having complex and irregular shapes as stated in column 1, lines 10 and 11. The resolution of this problem proposed by Childers et al. is to use vapor compression. Essentially, an inert gas is used to compress the vapor sterilant that is diffused into closed and open ended lumens. Air acts as a piston which pushes and compresses the sterilant vapor. As such, the sterilant vapor becomes more effective. By contrast, in the subject application, it is only after the removal of a sterilant and after a further evacuation to remove the sterilant that the gas is introduced to effect the flushing step to remove any condensed water. Thus, in the present application, the flushing of the chamber to remove condensation takes place in the absence of a sterilant. It is respectfully submitted that this difference is important. If the "flushing" step in Childers et al. was performed in the absence of a sterilant, it would not be of any purpose as the entire purpose of the Childers et al. invention is to improve sterilant penetration. To this end, it is respectfully submitted that the invention as claimed would not be obvious in view of Robitaille et al. and Childers et al. whether taken individually or in combination, since Childers et al. is directed to a completely different sterilization than Robitaille et al. and therefore there would be no motivation for a person of ordinary skill in the art looking for solutions to problems in an ozone sterilization process to consider the Childers et al. reference which does not mention ozone sterilization and is mainly directed to hydrogen peroxide sterilization. This distinction has been drawn out even more clearly in new claim 17 which explicitly claims the absence of a sterilant during the flushing step.

In regard to the dependant claims, these claims should be considered allowable by virtue of their dependency. Furthermore they present additional patentable subject

matter. For example with respect to claims 3 and 12, no step of flushing with oxygen is seen in the prior art and, with respect to claims 4, 13 and 18, a repeated flushing step is also not disclosed or rendered obvious.

Based on the above, it is respectfully requested that the prior art rejections be withdrawn, the claims allowed and the application pass to issue. If the Examiner should have any additional concerns regarding the allowance of the application which can be readily addressed, she is cordially invited to contact the undersigned at the number provided below in order to further prosecution.

Respectfully submitted,



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